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Atty. Dkt. No. 048331-1707

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims set forth above, claims 1, 11, 24 and 124-169 are currently pending in the instant application. All claim amendments find support in the application specification and in the claims as originally filed. In particular, support for the amendments specifying that the amount of amplified product is at least about 10+ fold greater than the amount of template DNA put into the mixture can be found for example at page 6, lines 18-21; support for the amendments specifying that the reaction mixture include two forms of DNA polymerase, and more specifically a wild-type T7 DNA polymerase and a T7 DNA polymerase modified to have reduced 3' to 5' exonuclease activity can be found for example at page 5, lines 13-17 (see also page 13, line 23 to page 24, line 4 which discloses ratios); support for the amendments specifying exponential amplification of template DNA can be found for example at page 5, line 23 to page 6, line 27; support for amendments specifying the constant temperature can be found for example at page 5, lines 7 to 9 and at page 8, lines 13 to 15; and support for amendments specifying that the reaction mixture include a nucleoside diphosphokinase, an inorganic pyrophosphatase, an ATP regeneration system, a ligase, potassium glutamate, DMSO and/or dextran polymer can be found for example at page 7, lines 16 to 28. Accordingly, the amendments raise no issues of new matter.

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Rejection of Claims 1 and 11 Under 35 U.S.C. § 102(b) over Scherzinger et al.;Engler et al.; and Applegren et al.

The rejection of claims 1 and 11 under 35 U.S.C. §102(b) as allegedly being anticipated by Scherzinger et al. (Eur. J. Biochem 72, 543-558 (1977), hereinafter "Scherzinger et al."); Engler et al. (the Journal of Biological Chemistry (1993), vol. 258, No. 18, pp. 11197-11203, hereinafter "Engler et al.") and Applegren et al. (Journal of Cellular Biochemistry 59:91-107 (1995)), hereinafter "Applegren et al.") is respectfully traversed.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*, MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only once that *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. *See, e.g.*, *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The instant claims are directed to a method of amplifying DNA wherein the method is performed under conditions such that the amount of amplified product is at least about 10-fold greater than the amount of template DNA. The references of record merely disclose that DNA can be replicated and none disclose any method by which DNA can be amplified such that amount of amplified product is at least about 10-fold greater than the amount of template DNA as required by the claims. Accordingly, Applicant respectfully submits that no *prima facie* anticipation rejection has been established, and therefore requests that the rejections over Scherzinger et al.; Engler et al.; and Applegren et al be withdrawn.

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Rejection of Claim 24 Under 35 U.S.C. § 103(a) over Scherzinger et al.in view of Sorge et al.

The rejection of claim 24 under 35 U.S.C. §103(a) as allegedly being unpatentable over Scherzinger et al. in view of Sorge et al. (U.S. Patent No. 5, 556,772, hereinafter "Sorge et al.") is respectfully traversed.

In order to establish a *prima facie* case of obviousness, it is necessary that the prior art disclose each and every limitation of the claim, that there is a reasonable expectation of success, and that there is some motivation, either in the prior art references or in the knowledge of the person of ordinary skill in the art, to make the asserted combination or modify or combine the reference teachings (MPEP 2142).

The invention encompassed by claim 11 is based, at least in part, on the surprising discovery that incubating template DNA with reaction mixtures specified in the instant claims under the proper conditions results in an unexpectedly large amount of DNA synthesis without a need for exogenously added oligonucleotide primers.

As the Examiner acknowledged, the primary Scherzinger et al., reference does not teach a method in which the reaction mixture comprises a T7 DNA polymerase modified to have reduced 3' to 5' exonuclease activity. The Examiner alleges that it would be obvious to arrive at the instant invention by combining the DNA polymerase composition taught by Sorge et al., with the reaction mixture of Scherzinger et al. Applicant respectfully submits that the rejection fails because the cited references provide no teaching or suggestion that would motivate one of ordinary skill to combine the references to arrive at the instantly claimed method of amplification which does not require exogenously added primers, nor is there any teaching that would provide a reasonable expectation of success.

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Sorge et al., discloses a method of DNA amplification that requires exogenously added oligonucleotide primers. This requirement of the Sorge methods is clearly stated in the Summary of the Invention:

Other reagents required for polynucleotide synthesis include nucleotide triphosphates (dNTPs), polynucleotide primers, a synthesis template and the like.

Column 2, lines 39-41 (emphasis added). Moreover, each of the examples disclosed in the patent utilize exogenously added oligonucleotide primers and there is no teaching or suggestion that the methods could be used without such primers. Accordingly, Applicant respectfully submits that the Sorge reference would motivate one of ordinary skill against using the DNA polymerases of the reference in a method that does not require exogenously added oligonucleotide primers as recited in the instant claims. Furthermore, because the methods of the Sorge et al., patent depend on exogenously added oligonucleotide primers for amplification, there would be no reasonable expectation of successfully practicing the claimed method not requiring such primers.

Accordingly, because the required motivation to combine and expectation of success are lacking Applicant respectfully submits that a *prima facie* obviousness rejection of the instant claims fails. Therefore reconsideration and withdrawal of the rejection is respectfully urged.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

By _____



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